

WHAT IS CLAIMED IS:

1. A pharmaceutical composition suitable for oral administration to a human, comprising:

from about 0.5% to about 60% by weight of a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid;

(ii) from about 10% to about 95% by weight of a non-reducing sugar selected from the group consisting of mannitol, xylitol, sorbitol, inositol, sucrose and trehalose;

(iii) from about 2% to about 60% by weight of a binder selected from the group consisting of microcrystalline cellulose, hydroxypropyl cellulose, methyl cellulose, hydroxypropyl methyl cellulose and polyvinylpyrrolidone;

(iv) from about 0.5% to about 15% by weight of a disintegrant selected from the group consisting of starch, modified starch, croscarmellose sodium, crospovidone and sodium starch glycolate; and

(v) from about 0.1% to about 7% by weight of a lubricant selected from the group consisting of calcium stearate, magnesium stearate, stearic acid, talc, hydrogenated vegetable oil and sodium stearyl fumarate.

2. The pharmaceutical composition of claim 1, wherein said composition is in the form of a tablet.

3. The pharmaceutical composition according to claim 1, comprising:

(i) from about 0.5% to about 60% by weight of a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid;

(ii) from about 30% to about 95% by weight of mannitol;

(iii) from about 2% to about 40% by weight of hydroxypropyl methyl cellulose;

(iv) from about 1% to about 15% by weight of sodium starch glycolate;
and

(v) from about 0.25% to about 7% by weight of sodium stearyl fumarate.

4. The pharmaceutical composition according to claim 1, comprising:

(i) from about 10% to about 60% by weight of a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid;

(ii) from about 10% to about 50% by weight of mannitol;

(iii) from about 20% to about 60% by weight of microcrystalline cellulose;

(iv) from about 0.5% to about 10% by weight of croscarmellose sodium; and

(v) from about 0.1% to about 3% by weight of magnesium stearate.

5. The pharmaceutical composition according to claim 1, wherein said a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid is 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid monosodium salt trihydrate.

6. The pharmaceutical composition according to claim 1, wherein said a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid is anhydrous 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid monosodium salt.

7. The pharmaceutical composition according to claim 1, comprising:

(i) from about 0.5% to about 50% by weight of a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid;

(ii) from about 20% to about 90% by weight of a non-reducing sugar selected from the group consisting of mannitol, xylitol, sorbitol, inositol, sucrose and trehalose;

(iii) from about 5% to about 50% by weight of a binder selected from the group consisting of microcrystalline cellulose, hydroxypropyl cellulose, methyl cellulose, hydroxypropyl methyl cellulose and polyvinylpyrrolidone;

(iv) from about 0.5% to about 10% by weight of a disintegrant selected from the group consisting of starch, modified starch, croscarmellose sodium, crospovidone and sodium starch glycolate; and

(v) from about 0.25% to about 5% by weight of a lubricant selected from the group consisting of calcium stearate, magnesium stearate, stearic acid, talc, hydrogenated vegetable oil and sodium stearyl fumarate.

8. The pharmaceutical composition of claim 7, wherein said composition is in the form of a tablet.

9. The pharmaceutical composition according to claim 7, comprising:

(i) from about 0.5% to about 50% by weight of a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid;

(ii) from about 40% to about 90% by weight of mannitol;

(iii) from about 5% to about 30% by weight of hydroxypropyl methyl cellulose;

(iv) from about 1% to about 10% by weight of sodium starch glycolate; and

(v) from about 0.5% to about 5% by weight of sodium stearyl fumarate.

10. The pharmaceutical composition according to claim 7, comprising:
- (i) from about 15% to about 40% by weight of a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid;
 - (ii) from about 20% to about 40% by weight of mannitol;
 - (iii) from about 30% to about 50% by weight of microcrystalline cellulose;
 - (iv) from about 0.5% to about 5% by weight of croscarmellose sodium;
- and
- (v) from about 0.25% to about 2% by weight of magnesium stearate.

11. The pharmaceutical composition according to claim 7, wherein said a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid is 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid monosodium salt trihydrate.

12. The pharmaceutical composition according to claim 7, wherein said a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid is anhydrous 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid monosodium salt.

13. The pharmaceutical composition according to claim 7, comprising:
- (i) from about 1% to about 30% by weight of a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid;
 - (ii) from about 30% to about 80% by weight of a non-reducing sugar selected from the group consisting of mannitol, xylitol, sorbitol, inositol, sucrose and trehalose;
 - (iii) from about 10% to about 45% by weight of a binder selected from the group consisting of microcrystalline cellulose, hydroxypropyl cellulose, methyl cellulose, hydroxypropyl methyl cellulose and polyvinylpyrrolidone;

(iv) from about 0.5% to about 8% by weight of a disintegrant selected from the group consisting of starch, modified starch, croscarmellose sodium, crospovidone and sodium starch glycolate; and

(v) from about 0.5% to about 3% by weight of a lubricant selected from the group consisting of calcium stearate, magnesium stearate, stearic acid, talc, hydrogenated vegetable oil and sodium stearyl fumarate.

14. The pharmaceutical composition of claim 13, wherein said composition is in the form of a tablet.

15. The pharmaceutical composition according to claim 13, comprising:

(i) from about 1% to about 30% by weight of a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid;

(ii) from about 50% to about 80% by weight of mannitol;

(iii) from about 10% to about 20% by weight of hydroxypropyl methyl cellulose;

(iv) from about 2% to about 8% by weight of sodium starch glycolate; and

(v) from about 1% to about 3% by weight of sodium stearyl fumarate.

16. The pharmaceutical composition according to claim 13, comprising:

(i) from about 20% to about 30% by weight of a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid;

(ii) from about 25% to about 35% by weight of mannitol;

(iii) from about 35% to about 45% by weight of microcrystalline cellulose;

(iv) from about 0.5% to about 1.5% by weight of croscarmellose sodium; and

(v) from about 0.5% to about 1% by weight of magnesium stearate.

17. The pharmaceutical composition according to claim 13, wherein said a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid is 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid monosodium salt trihydrate.

18. The pharmaceutical composition according to claim 13, wherein said a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid is anhydrous 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid monosodium salt.

19. The pharmaceutical composition according to claim 15, comprising:

(i) from about 3% to about 26% by weight of a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid;

(ii) from about 53% to about 76% by weight of mannitol;

(iii) about 13% to about 15% by weight of hydroxypropyl methyl cellulose;

(iv) about 4% to about 6% by weight of sodium starch glycolate; and

(v) about 2% by weight of sodium stearyl fumarate.

20. The pharmaceutical composition of claim 19, wherein said composition is in the form of a tablet.

21. The pharmaceutical composition according to claim 19, wherein said a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene--1,1-

bisphosphonic acid is 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid monosodium salt trihydrate.

22. The pharmaceutical composition according to claim 19, wherein said a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid is anhydrous 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid monosodium salt.

23. The pharmaceutical composition according to claim 16, comprising:

- (i) about 26% by weight of a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid;
- (ii) about 32% by weight of mannitol;
- (iii) about 40% by weight of microcrystalline cellulose;
- (iv) about 1% by weight of croscarmellose sodium; and
- (v) about 0.6% by weight of magnesium stearate.

24. The pharmaceutical composition of claim 23, wherein said composition is in the form of a tablet.

25. The pharmaceutical composition according to claim 23, wherein said a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid is 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid monosodium salt trihydrate.

26. The pharmaceutical composition according to claim 23, wherein said a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid is anhydrous 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid monosodium salt.

27. A process for preparing a pharmaceutical composition suitable for oral administration to a human comprising:

- (i) forming a mixture of from about 0.5% to about 60% by weight of a pharmaceutically acceptable salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid, from about 10% to about 95% by weight of a non-reducing sugar selected from the group consisting of mannitol, xylitol, sorbitol, inositol, sucrose and trehalose, from about 2% to about 60% by weight of a binder selected from the group consisting of microcrystalline cellulose, hydroxypropyl cellulose, methyl cellulose, hydroxypropyl methyl cellulose and polyvinylpyrrolidone; from about 0.5% to about 15% by weight of a disintegrant selected from the group consisting of starch, modified starch, croscarmellose sodium, crospovidone and sodium starch glycolate; and from about 0.1% to about 7% by weight of a lubricant selected from the group consisting of calcium stearate, magnesium stearate, stearic acid, talc, hydrogenated vegetable oil and sodium stearyl fumarate; and
- (ii) compressing said mixture into a tablet.